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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,723	06/20/2005	Michaela Hoehne	65084.000013	5109

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EXAMINER	
PAGE, BRENT T	
ART UNIT	**PAPER NUMBER**
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,723	HOEHNE ET AL.	
	Examiner	Art Unit	
	Brent Page	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *10-13 and 17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,14-16,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *IDS 01/13/2006*.

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 01/23/2007 is acknowledged. The traversal is on the ground(s) that the technical feature is a genetic modification which leads to the reduction of the activity of one or more endogenous SSIII, BEI, or BEII proteins in a plant cell. This is not found persuasive because the starch of Group II could be obtained through methods that do not reduce this activity, for example methods that chemically alter the starch and not be a patentably distinct starch.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 14-16 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transforming potato plants with specific antisense fragments from potato starch synthase III, potato starch branching enzyme I and potato starch branching enzyme II, does not reasonably provide enablement for the transformation of any plant with any gene that reduces the activity of these three enzymes, not any plant with these three genes from any plant source as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn broadly to any genetically modified plant cell, any plant comprising said cell, a method for generating any genetically modified plant, a method for modifying starch of any plant and propagation material of said plants, wherein all comprise any genetic modification of any plant leading to the reduction of the activity of one or more endogenously occurring SSIII proteins, BEI proteins, or BEII proteins in comparison to corresponding plant cells of wild-type plants which have not been genetically modified.

In contrast, the specification only provides guidance for transforming potato plants with specific antisense fragments from potato starch synthase III, potato starch branching enzyme I and potato starch branching enzyme II, and does not provide guidance for the transformation of any other plants with any other nucleic acid sequences to reduce the activity of the aforementioned enzymes.

The synthesis of starch in plants is complex and unpredictable. In a review of the regulation of starch metabolism in plants Tetlow et al (2004 Journal of Experimental Botany 55(406):2131-2145) discuss the developments that help understand the regulation of starch metabolism in higher plants. Tetlow et al disclose that the function of any particular starch depends on the type of plastid it is synthesized in and the type of plant tissue it is derived from (see page 2131 Column 2, lines 3-5). Tetlow et al also disclose that only a few genetic variations that lead to known phenotypes are even known for starch branching enzymes as

evidenced by the statement "To date, only mutations in SBEII isoforms give clear phenotypes, and in monocots this is confined to SBEIIb mutants" (see page 2134 second column, last paragraph). Furthermore the affect these variations have on starch derived from the endosperm is unpredictable. Tetlow et al disclose a mutant of SBEIIa that displayed a clear phenotype in leaf starch but showed no alterations in the storage starch of the endosperm (See page 2134 Column 2, last paragraph, for example). Tetlow et al further disclose that other genes are capable of affecting the expression of at least SBEIIb, but not all of these genes are known (see page 2135, 1st column, 3rd paragraph, for example). Without a clear guidance as to the specific genetic variation, it would be undue experimentation to evaluate all genetic variations of all genes affecting the level of SBEI, SBEII, and Starch Synthase III enzymes as broadly claimed.

The effect of starch biosynthesis genes on amylose content and structure is unpredictable. Recent studies have shown that GBSSI genes in many plant species have more than one isoform, and further that different isoforms are present in different plant tissues and therefore have different effects on the starch content of the endosperm. Patron et al (Plant Physiology 2002, 130: 190-198) disclose a study detailing the altered pattern of amylose accumulation in low-amylose barley cultivars with mutant alleles of the different isoforms of barley GBSSI (see page 190 1st full paragraph, page 191, last full paragraph, page 192, last full paragraph). Edwards et al (The Plant Cell 2002, 14: 1767-1785) disclose the characterization of the discrete forms of amylose produced by different isoforms of GBSSI in pea (see page 1767, last full paragraph, page 1768 1st and

second full paragraphs, page 1771 3rd full paragraph, and page 1775 in its entirety).

Given the state of the art, the disclosures by Tetlow et al, Patron et al and Edwards et al, and the unpredictability as discussed above, it would be undue experimentation for one of skill in the art to evaluate all nucleic acid molecules from all genes from all plants for their ability to reduce the activity of SBEI, SBEII, and SSIII, and to produce plants having a specific starch property using these nucleic acid molecules as broadly claimed.

Claim 1-9, 14-16 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn broadly to any genetically modified plant cell, any plant comprising said cell, a method for generating any genetically modified plant, a method for modifying starch of any plant and propagation material of said plants, wherein all comprise any genetic modification of any plant leading to the reduction of the activity of one or more endogenously occurring SSIII proteins, BEI proteins, or BEII proteins in comparison to corresponding plant cells of wild-type plants which have not been genetically modified.

In contrast the specification only provides the description of specific antisense fragments from potato starch synthase III, potato starch branching

enzyme I and potato starch branching enzyme II, and does not provide descriptions of any other nucleic acid sequences capable of reducing the activity of the aforementioned enzymes.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or

relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 112 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 14-16, and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4 and 5 recite "leading(or "leads") to the reduction of activity". It is unclear what limitation Applicant intends for the descriptor "leading". It is unclear when the reduction of activity must take place and whether additional steps must be undertaken to effect such reduction of activity.

Claims 2, 5-7, 14-15 all recite either "a" plant cell or "a" plant, respectively "according to..." which lacks proper antecedence. When referring to the plant or the plant cell according to a specific claim the word ---the--- should proceed "plant" or "plant cell" accordingly. New Matter should be avoided.

Claims 3 and 9 recite "plant cells" which lacks antecedence. Proper antecedence would refer to ---the plant cell---. New Matter should be avoided.

Claims 8, 16, and 21 all recite "plants" which lacks antecedence. Proper antecedence would refer to ---the plant---. New Matter should be avoided.

Claims 9 and 21 recite "proteins with the enzymatic activity of at least one SSIII, BEI and/or BEII protein or their fragments". It is not clear what is sufficient for enzymatic activity, or what is sufficient for enzymatic activity of a fragment. For the purposes of examination, the Examiner interprets "or their fragments" to read on sequences that encode proteins with no enzymatic activity. It is further unclear whether "and/or" is intended as a limitation in the claim and whether or not Applicant intended to limit the claim to at least two protein fragments, or just one. For the purposes of examination, no limitation is read into the "and/or" and it is considered to read on any one nucleic acid encoding one protein fragment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-9, 14-16 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Broglie et al (US Patent 6376749).

The claims are drawn broadly to a genetically modified plant cell, a plant comprising said cell, a method for generating a genetically modified plant, a method for modifying starch of a plant and propagation material of said plants, wherein all comprise any genetic modification of any plant leading to the reduction of the activity of one or more endogenously occurring SSIII proteins, BEI proteins, or BEII proteins in comparison to corresponding plant cells of wild-type plants which have not been genetically modified, wherein the genetically modified plant cell synthesizes a modified starch comprising starch which after gelatinization of a 6% suspension in water forms a gel with a gel strength that is increased by at least 300% in comparison with the gel strength of starch extracted from wild-type cells, wherein the genetic modification comprises the introduction of one or more foreign nucleic acid molecules, wherein one or more molecules are used which encode proteins with the enzymatic activity of at least one SSIII, BEI and/or BEII protein, wherein the plant is a starch storing plant.

Broglie et al teach a maize plant which stores starch in its endosperm transformed with an antisense construct for the inhibition of the endogenous starch branching enzyme I and II activity using at least a portion of starch branching enzyme I and also using at least a portion of starch branching enzyme II in sense or antisense orientation, wherein the resulting corn has modified starch content that has an increased viscosity compared to wild-type. (see claims 1, 5-6 and 7-9 in particular, Table 3, and Examples 1 and 3, for example). Broglie et al do not measure the starch by gelatinizing a 6% suspension in water and forming a gel, however, absent evidence to the contrary, it is inherent if the starch was measured in this way that it would have a gel strength that is increased by at least 300% in comparison with the gel strength of starch extracted from wild-type cells.

Claims 1-9, 14-16 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (WO 99/66050).

The claims are drawn broadly to a genetically modified plant cell, a plant comprising said cell, a method for generating a genetically modified plant, a method for modifying starch of a plant and propagation material of said plants, wherein all comprise any genetic modification of any plant leading to the reduction of the activity of one or more endogenously occurring SSIII proteins, BEI proteins, or BEII proteins in comparison to corresponding plant cells of wild-type plants which have not been genetically modified, wherein the genetically modified plant cell synthesizes a modified starch comprising starch which after gelatinization of a 6% suspension in water forms a gel with a gel strength that is

increased by at least 300% in comparison with the gel strength of starch extracted from wild-type cells, wherein the genetic modification comprises the introduction of one or more foreign nucleic acid molecules, wherein one or more molecules are used which encode proteins with the enzymatic activity of at least one SSIII, BEI and/or BEII protein, wherein the plant is a starch storing plant, wherein the plant is a potato plant.

Edwards et al teach a potato plant transformed with a construct comprising an antisense fragment of starch synthase II and starch synthase III wherein the endogenous activity of starch synthase II and starch synthase III is strongly reduced and the starch is modified wherein the reduced gelatinization onset temperature indicates the gel strength is increased relative to that of wild-type (see pages 16-18, claims 6-10 and 12-13 in particular). Edwards et al do not measure the starch by gelatinizing a 6% suspension in water and forming a gel, however, absent evidence to the contrary, it is inherent if the starch was measured in this way that it would have a gel strength that is increased by at least 300% in comparison with the gel strength of starch extracted from wild-type cells.

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

Phuong Bui 3/13/07
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PRIMARY EXAMINER